

8EHQ-0901-14822J

MR 5159

51576

September 14, 2001

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SUBJECT: TSCA 8(e) SUBMISSION

Dear Sir or Madam,

\_\_\_\_\_ (" ") is submitting additional data which we believe to be reportable under TSCA 8(e). This information concerns, \_\_\_\_\_ an experimental pyrethroid insecticide identified as \_\_\_\_\_

\_\_\_\_\_ has been assigned CAS Number \_\_\_\_\_  
\_\_\_\_\_ has recently imported \_\_\_\_\_ solely for R&D testing purposes on behalf of \_\_\_\_\_  
\_\_\_\_\_ (" ").

The first report of adverse effects from this test substance was sent to your Agency on \_\_\_\_\_, Document Control Number \_\_\_\_\_. A second report on a preliminary dose range-finding study was submitted on \_\_\_\_\_.

28-day oral toxicity study of \_\_\_\_\_ in rats

Materials and Methods

Animals: Crj:CD(SD) rats, 5 weeks-old (at start of administration), both sexes, (6/sex/dose)  
Pre-dose fasting: None

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Doses:	0, 60, 120, 500 and 5000 ppm Additionally, 6 rats/sex/dose group in dose levels of 0 (controls) and 5000 ppm were maintained untreated for 14 days, and were used as the recovery group.
Administration route:	oral (in feed)
Administration period:	28 days
Range of body weights:	males: 135-155 g; females: 108-129 g
Observation periods:	once daily in the morning for 29 days
Procedures performed:	abnormal clinical signs; body weights (once weekly and on the day of necropsy) , food consumption, urinalysis, hematology, blood chemistry, necropsy, organ weights, histopathological examination

Necropsy was performed after over-night fasting following the last administration of the test substance.

## Results

Tremors were observed in rats of both sexes dosed at 5000 ppm (males at 474.7 mg/kg/day; and in females at 474.6 mg/kg/day; see summary of results on page 3 for specifics). Tremors first appeared on day 2 and persisted until the end of the treatment period.

Effects were noted in the livers of male rats at 500 ppm (48.5 mg/kg/day) and in females at 5000 ppm (474.6 mg/kg/day). These effects were increased absolute and relative liver weights (compared to the same weights found in the control animals).

All abnormal signs/symptoms disappeared or declined in the recovery groups, therefore the effects of the test substance appeared to be reversible by the first day of the recovery period for the tremors and on the day of necropsy for the liver effects. None of the animals died in this study. The NOAEL was determined to be 120 ppm (11.5 mg/kg/day) for males and 500 ppm (48.5 mg/kg/day) for females.

Please see table summarizing study results below.

### Summary of study results

Summary of Study Results						
Dosage	60 ppm	120 ppm	500 ppm		5000 ppm	
No. of animals	6/sex	6/sex	6/sex		6/sex*	
Mortality	0	0	0		0	
Clinical signs	0	0	0		tremor ♂      ♀	
			Week 1		3-6/12	3-5/12
			Week 2		2-4/12	1-4/12
			Week 3		2-4/12	1-3/12
			Week 4		0-2/12	0-1/12
Necropsy	0	0	effects on liver (♂)      (♀)		effects on liver (♂)      (♀)	
		↑ Absolute liver weights	119%	n/a	151%	117%
		↑ Relative liver weights	115%	n/a	153%	123%
		Enlarged liver	2/6	n/a	6/6	3/6
		Hypertrophy	1/6	n/a	6/6	3/6

\* 6 treatment and 6 recovery animals

### Substantiation of CBI Claims

We wish to substantiate                      claims that certain information in this letter be treated as Confidential Business Information ("CBI"). All information deleted from the sanitized version of this letter (copy attached) should be treated as CBI.                      wishes to protect its CBI during the commercial development of this chemical. Disclosure of this information would harm                      efforts to commercialize                      . Please refer to the attached copy of our letter to                      of your Agency which substantiates these CBI claims.

Should you have questions concerning this submission, please do not hesitate to contact me at (    ) -    by telephone, (    ) -    by telefax or via e-mail through    .

Sincerely yours,

Enclosure: (1)

cc: